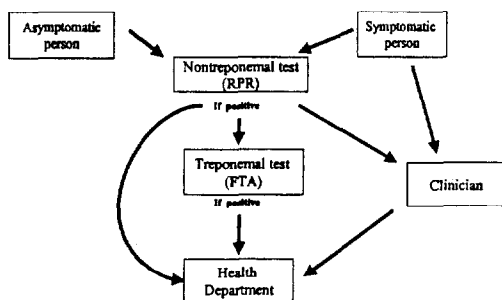


Early Cases of Syphilis Identified through Attempted Blood Bank Donation and Estimate of Risk

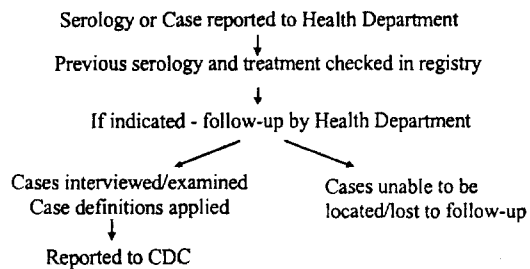
Division of STD Prevention
National Center for HIV, TB, STD Prevention
Centers for Disease Control and Prevention

- Overview of syphilis surveillance system
- Information on reported cases identified by donor screening
- Risk estimate of transfusion related cases

Syphilis Reporting to the Health Departments



Syphilis Surveillance and Reporting to CDC



Syphilis Surveillance Systems

NETSS - National Electronic Telecommunications System for Surveillance

- First implemented in 1992
- Collects additional data not previously available
- Source of report indicated

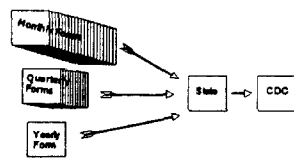
STDMR - STD Morbidity Report System

- Eventually will be replaced by NETSS
- Collects reports as aggregate data from all 50 states
- Detailed information not available for individual cases

Syphilis Surveillance Systems

STDMR

- Aggregate data
- 1983 → phasing out
- Handcopy
- Different Reporting Periods
- Age, Race, Sex



NETSS

- Individual case data
- 1992 → phasing in
- Electronic
- Timely
- More detailed data



Estimate of Donation-Identified Cases

- 'Source of report' field from NETSS data
- Adjustment made because not all states use NETSS
- Estimation factor = STDMR cases/NETSS cases

Actual and Estimated cases of early syphilis identified by blood donation screening, 1995 - 1998

	Total reported cases		Estimation Factor	Number of cases	
	STDMR	NETSS		Actual	Estimate
Primary/Secondary					
1995	16543	5595	2.96	19	56
1996	11388	4813	2.37	15	36
1997	8556	5007	1.71	16	27
1998	6993	5334	1.31	17	23
P&S Total	43480	20749	—	67	142
Early Latent					
1995	26657	5114	5.21	70	365
1996	20187	6102	3.31	56	185
1997	16631	7115	2.34	62	145
1998	12613	10183	1.24	73	90
EL Total	76088	28514	—	261	785
P&S and EL Total	101720	49263	—	328	927

Plasma Centers vs. Blood Banks

- NETSS does not distinguish blood banks from plasma centers
- Interview of STD Program Directors in 4 states that accounted for most donation-identified cases:

"Almost all identified from plasma centers" - 1

"Almost all identified from blood banks" - 1

"Proportion from blood banks slightly less than from plasma centers" - 2

**Percentage of all Syphilis Cases
Identified by Blood Donation
Screening, 1995-1998**

Type of Case	Total Reported	Identified by Blood Donation	
		N	%
1° & 2°	23,335	142	.6
Early Latent	76,088	785	1.0

**Estimate of Potentially
Infectious Donors**

Assumptions:

- 1° & 2° cases - all bacteremic
- Early latent cases - 5% bacteremic

Estimates:

$$\begin{array}{l} 1^\circ \text{ \& } 2^\circ \text{ cases} - 142/4 \times 1 = 36 \\ \text{Early latent cases} - 785/4 \times .05 = 10 \end{array} \quad \left. \vphantom{\begin{array}{l} 1^\circ \text{ \& } 2^\circ \text{ cases} \\ \text{Early latent cases} \end{array}} \right\} 46$$

**Estimate of Transfusion-Related
Cases if no Screening**

Assumptions:

- 2 components/ donation (46 x 2 = 92)
- Risk from transfusion = .001(stored) to .05 (fresh)

Estimates:

$$\begin{array}{l} 92 \times .001 = 0.09 \text{ cases per year} \\ 92 \times .05 = 4.6 \text{ cases per year} \end{array}$$

Summary

- Recent changes in surveillance have allowed identification of syphilis cases detected through blood donation centers
- From 1995-1998, 927 cases of early syphilis were detected
- 0.9- 4.6 transfusion cases/year could have occurred if syphilis screening were not performed

CDC's plan of Syphilis transfusion studies to address the discrepancies between their studies and those conducted by American Red Cross.

Background:

The issue: CDC has detected treponemal DNA in the blood of patients with incubating, primary, secondary, and early latent syphilis, but the Red Cross studies of platelet concentrates from seropositive donors have failed to detect this DNA. One possibility is that the specimens from the Red Cross have been from persons with late latent disease or treated syphilis and would, therefore, not contain treponemes. Another possibility is that the treponemes are not present in the platelet concentrates but might be present in other components.

Based on these considerations, CDC proposes the following laboratory studies:

1. Obtain units of discarded whole blood from the Red Cross. Spike them with *T. pallidum*, then ask the Red Cross to process them into blood components. Test each component for treponemal DNA by PCR.
2. Assay spiked blood for infectivity by rabbit inoculation model.
3. Expand the current Red Cross study to areas of higher syphilis incidence in hopes of collecting a donation from a person with infectious syphilis. Also test all components derived from seropositive donations, not just platelet concentrates.
4. Consider examining donations from South Africa, where the incidence of syphilis is much higher than in the US and where CDC has good collaborations we would need to determine that the processing of blood in South Africa is similar to what is done in the US.

In addition to these laboratory studies, additional clinical and epidemiological studies of seropositive donors might be useful. For example, what proportion of these donors actually have infectious syphilis? Of those with infectious syphilis, what proportion are whole blood donors versus plasma donors? Were these donors actually symptomatic at the time of donation?

CDC Speakers:

CDC speakers will discuss current results and proposed studies.

OPEN PUBLIC HEARING

67th Meeting
September 14-15, 2000
Hilton-Gaithersburg
620 Perry Parkway
Gaithersburg, MD 20877

Martin Ruta, J.D., Ph.D.

Blood Products Advisory Committee Meeting - September 14-15,
2000

III. Current Utility of Screening Blood Donors for Antibodies to Syphilis

Questions for the Committee

1.a. Do committee members agree that current scientific data are insufficient to warrant discontinuation of donor testing for antibodies to syphilis ?

1.b. If so, committee members are asked to comment on the adequacy of the additional studies, as proposed, to resolve the value of testing for antibodies to syphilis in preventing the transmission of syphilis through blood transfusion.

2. Do committee members believe that donor testing for antibodies to syphilis should be retained as a surrogate marker of deferrable high risk behavior, even if it is proven that such testing no longer is useful for prevention of transfusion transmission of syphilis?

IV. CLASSIFICATION OF HLA DEVICES

Sheryl Kochman

Chief, Devices Review Branch, Division of Blood Applications

67th Meeting
September 14-15, 2000
Hilton-Gaithersburg
620 Perry Parkway
Gaithersburg, MD 20877